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No. 95-

IN THE
Supreme Court of the United States
OCTOBER TERM, 1995

SCHERING CORPORATION,
Petitioner,

v.

FOOD AND DRUG ADMINISTRATION,
Respondent.

Petition for Writ of Certiorari to the United States Court of Appeals for the Third Circuit

PETITION FOR WRIT OF CERTIORARI

ROBERT P. REZNICK
Counsel of Record
HUGHES HUBBARD & REED
1300 I Street, N.W.
Suite 900 West
Washington, D.C. 20005
(202) 408-3740
Counsel for Petitioner

Of Counsel

JOSEPH C. CONNORS
MAUREEN O. CHELIUS
SCHERING CORPORATION
2000 Galloping Hill Road
Kenilworth, NJ 07033
(908) 298-4741

WILSON - EPES PRINTING CO., INC. - 789-0096 - WASHINGTON, D.C. 20001

QUESTIONS PRESENTED

"Bioequivalence" is the statutory standard of comparable safety and efficacy between a generic drug and the pioneer drug it copies that must be met before the Food and Drug Administration ("FDA") may approve any generic drug for sale in the United States. The bioequivalence requirement was added by, and defined in, the 1984 "Hatch-Waxman Amendments" to the Federal Food, Drug, and Cosmetic Act.

1. Did the court of appeals err in concluding that FDA, by regulation, could attempt to promote generic drug approvals by promulgating a more lenient definition of bioequivalance than that contained in the Hatch-Waxman Amendments?

2. Did the court of appeals wrongly defer to FDA's redefinition of the bioequivalence requirement pursuant to *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), where the redefinition was a significant and unacknowledged departure from the definition codified by Congress, and where the court had already rejected FDA's understanding of the purposes of the bioequivalence requirement as inconsistent with the Hatch-Waxman Amendments?

RULE 29.1 STATEMENT

Petitioner Schering Corporation is a wholly-owned subsidiary of Schering-Plough Corporation. Petitioner has the following non-wholly owned subsidiaries: P.T. Schering-Plough Indonesia; Schering-Plough (Proprietary) Limited (South Africa); Essex Pharmor S.A. (Greece); Fulford (India) Limited; Schering-Plough Korea Corporation; Essex Farmaceutica, S.A. (Colombia); Industria Quimica e Farmaceutica Schering-Plough Ltda. (Brazil); Shanghai Schering Plough Pharmaceutical Company, Ltd. (China).

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OPINIONS BELOW

The opinion of the United States Court of Appeals for the Third Circuit is reported at 51 F.3d 390 (1995), and is reprinted at pages 1a-21a of the Appendix to this Petition ("App."). The opinion of the United States District Court for the District of New Jersey is reported at 866 F. Supp. 821 (1994), and is reprinted at App. 22a-32a.

JURISDICTION

The opinion and judgment of the court of appeals were entered on April 3, 1995. App. 1a. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

STATUTES AND REGULATIONS INVOLVED

The relevant portions of the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. §§ 355(j)(7)(A) and (B), and 355 (*l*), are reprinted at App. 50a. The relevant portions of the regulations of the Food and Drug Administration at issue in this case, 21 C.F.R. § 320.1(a) and (e) (1992), and their predecessor regulations, 21 C.F.R. § 320.1(a) and (e) (1977), are reprinted at App. 52a-53a.

STATEMENT OF THE CASE

This case involves the statutory framework pursuant to which all generic drugs are approved for sale in the United States. Specifically, it involves the statutory requirement that a generic drug be "bioequivalent" to the approved pioneer product which it copies before the generic may be introduced into commerce. The mandatory bioequivalence requirement was first added to the generic drug approval process by the 1984 "Hatch-Waxman Amendments" to the Federal Food, Drug, and Cosmetic Act, which revolutionized the generic drug approval process by expanding dramatically the universe of drugs for which generic copies might be approved. Generic drugs are not subject to full clinical testing for safety and effectiveness. The bioequivalence requirement, which the Hatch-Waxman Amendments not only added but also defined, ensured in the new era that all generic products, despite their limited testing, would be comparable to their pioneer drug products in all material respects.

FDA, which is charged by statute with approving generic drugs pursuant to the standards established by Congress, does not consider the Hatch-Waxman Amendments to establish a definition of bioequivalence which the agency must honor. Rather, believing that approval of generic copies of every pioneer drug is the paramount

objective of the new law, FDA has taken the position that it has discretion to approve generic drugs pursuant to whatever definition of bioequivalence it believes to be appropriate, whether or not that definition is as stringent as the one set out by Congress. This position was reflected in final regulations promulgated in 1992 which changed FDA's long-standing regulatory definition of bioequivalence and which departed from the one definition of bioequivalence set out in the statute.

The regime of administrative discretion to determine the criteria for generic drug approvals that the court of appeals has let FDA create is precisely what existed prior to the Hatch-Waxman Amendments. Imposition of a mandatory, defined bioequivalence requirement changed all that, however, and reflected Congress' assumption of a policymaking role in connection with its comprehensive overhaul of the generic drug approval process. Through the regulation at issue in this case, FDA has sought to recapture the discretion that Congress took from it eleven years ago. Moreover, in the exercise of that purported discretion, FDA has redefined bioequivalence in a manner that is less stringent than what Congress required.

A. The Statutory Scheme Authorizing Approval of Generic Drugs

1. *The ANDA Process*

Prior to 1984, manufacturers desiring to sell a generic copy of a drug approved after 1962 were required to submit a new drug application ("NDA")—the result of a rigorous, time consuming, and expensive process that requires among other things the submission of comprehensive animal and human clinical testing that shows that the drug is "safe" and "effective." *United States v. Generix Drug Corp.*, 460 U.S. 453 (1983); *see* 21 U.S.C. § 355(b)(1)(A); 21 C.F.R. Part 314. The Hatch-Waxman Amendments, Title I of the Drug Price Competition and Patent Term Restoration Act of 1984,

Pub. L. No. 98-417, 98 Stat. 1585, created an *abbreviated* new drug application ("ANDA") process through which FDA could approve generic drug products outside of the full NDA process. Under the 1984 legislation, the manufacturer or distributor of a generic drug product is freed from the clinical trials required of NDA applicants so long as it can demonstrate that the generic is "bioequivalent" to the already-approved "pioneer" drug it copies. *See* 21 U.S.C. § 355(j)(2)(A)(iv), (j)(3)(F). In terms spelled out expressly in the statute, the "bioequivalence" requirement is intended to guarantee that the effectiveness and the safety of the generic drug and the pioneer drug will not differ in any significant way. Bioequivalence is the bridge between the safety and efficacy data provided by the original manufacturer in the full NDA process and the generic copy, which has not been subjected to clinical testing, ensuring that the two products are mutually substitutable. App., *infra*, 11a-12a.

The statutory ANDA process created by the Hatch-Waxman Amendments is different from anything that previously existed. FDA had administratively created a version of the ANDA prior to 1984. Most notably for present purposes, however, under the preexisting regulatory regime no mandatory bioequivalence requirement existed. FDA was free to approve a generic drug based upon whatever showing that it deemed adequate, and the agency had complete discretion to decide on a product-by-product basis if a bioequivalence requirement was appropriate. *See* 21 C.F.R. § 320.50-.52 (1977). Where such a decision was made, however, bioequivalence had the specific, fixed definition set out in FDA's regulations. *See id.* § 320.1(e) (1977). The Hatch-Waxman Amendments completely changed this regulatory structure. That legislation made bioequivalence a mandatory, nonwaivable requirement that had to be satisfied in every case, and as a consequence made bioequivalence of central importance to the statutory scheme. App., *infra*, 15a, 19a, 52a.

2. *The Statutory Bioequivalence Requirement*

Bioequivalence goes beyond a simple static comparison of the chemical compositions of two drug products. Merely assuring an identity between two products' chemical composition does not guarantee that they will be substitutable for one another; differences in manufacture can cause differences in how the product works, and its side effects. *See United States v. Premo Pharmaceutical Lab., Inc.*, 511 F. Supp. 958, 963-65 (D.N.J. 1981) Accordingly, the statutory definition of bioequivalence focuses on the actual absorption of drug products by the body, seeking to ensure that the generic and the pioneer product have comparable safety and efficacy. Bioequivalence is defined in the statute as follows:

> A drug shall be considered to be bioequivalent to a listed drug if—
>
> (i) the *rate and extent of absorption* of the drug do not show a significant difference from the rate and extent of absorption of the listed [pioneer] drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses[.]

21 U.S.C. § 355(j)(7)(B)(i) (emphasis added).[1]

A nearly identical definition in terms of a product's rate and extent of absorption was contained in FDA's own 1977 regulations, *see* 21 C.F.R. § 320.1(e) (1977), which had been in force for fifteen years before being changed by the 1992 regulation challenged in this case. FDA has acknowledged that its former definition of bioequivalence was written in exclusive terms, and agrees that the Hatch-Waxman Amendments codified that defini-

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[1] Section 355(j)(7)(B)(ii), not relevant here, defines bioequivalence for generic controlled release products, whose *rate* of absorption differs intentionally from that of the listed drug. Both subsections are reproduced in the Appendix, infra, at 50a.

tion "in all pertinent respects." J.A. 19, 31.[2] The legislative history of the Hatch-Waxman Amendments is to the same effect, expressly referring to the 1977 regulatory definition as having been codified by the legislation. *See* App. 17a; H.R. Rep. No. 857, 98th Cong., 2d Sess. pt. 1, at 31 (1984) ("1984 House Report"), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2664; 54 Fed. Reg. 28,872, 28,882 (1989). Despite this, FDA contends in this case that the statutory definition of bioequivalence is not an exclusive definition but merely one illustration of how bioequivalence might be established.

Bioequivalence is "essential to the operation of the [Hatch-Waxman Amendments]," and acts "to ensure that generic drugs will be as safe and effective as their pioneer drug counterparts." App., *infra*, 11a, 15a. Its importance as a legislative and a policy matter cannot be denied. From the standpoint of statutory structure, imposition of a mandatory, defined, health and safety standard complements the simultaneous expansion of generic drug approvals.[3] From a medical standpoint, the need for a generic and its pioneer to satisfy the statutory standard of comparability arises whenever one brand of a

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[2] The following references herein to briefs and other filings will be to the record in the court of appeals: "FDA Br." refers to the brief of Food and Drug Administration; "Schering Reply Br." refers to the reply brief of Schering Corp.; and "J.A." refers to the Joint Appendix.

[3] The seriousness with which Congress approached bioequivalence, and required FDA to approach it, is reinforced by the fact that the "faking or doctoring [of] bioequivalence studies required for FDA approval to market generic drugs" is at the core of the recent generic drug scandals. *See Generic Drug Approval Process at the Food and Drug Administration: Hearings Before The Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 101st Cong., 2d Sess. 2 (1990) (opening statement of Rep. John D. Dingell). At the same hearing, Rep. Wyden commented: "What citizens want to know is when these drugs are safe and effective and bioequivalence is right at the heart of it." Hearing Tr. 26.

particular prescription medication is substituted for another. This indeed is commonplace, and often results from the practice of "generic substitution" by pharmacies, which can occur without the knowledge of the physician or patient.[4] *See, e.g., Foster v. American Home Prods. Corp.*, 29 F.3d 165, 169 (4th Cir. 1994). The bioequivalence requirement—a showing that the rate and extent of absorption of a pioneer product and its generic copy do not differ significantly—is thus essential to preserve public health and safety in an era of generic substitution. It assures that FDA, in approving an ANDA for an untested generic, a physician, in prescribing a generic, a pharmacist, in substituting a generic for the pioneer drug, and the patient, in using a generic, can be confident that the generic will perform in all material respects like the pioneer. App., *infra*, 11a.

B. FDA's Regulatory Redefinition of Bioequivalence

On July 20, 1989, FDA issued proposed regulations to implement certain provisions of the Hatch-Waxman Amendments, which by then had been in force for almost five years. *See* 54 Fed. Reg. 28,872 (1989). Among the proposals was a regulation purporting to define bioequivalence in terms that departed from both FDA's prior regulation and the text of the Hatch-Waxman Amendments. Although the statute and the then-effective regulations defined bioequivalence in terms of the rate and extent of *absorption* of a product, the new regulation deleted this accepted statutory and regulatory benchmark. Instead of absorption, it focused on the "availability" of a drug at the site of action:

> *Bioequivalence* means the absence of a significant difference in the *rate and extent* to which the active

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[4] "To contain drug costs, virtually every state has adopted laws and/or regulations that encourage the substitution of drug products." FDA, *Approved Drug Products With Therapeutic Equivalence Evaluations* v (13th ed. 1993).

> ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives *becomes available* at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. . . .

See id. at 28,938 (proposing new 21 C.F.R. § 320.1(e) (1992)) (first emphasis in original). *See* App., *infra*, 53a. Schering filed comments objecting to the proposed regulation, *inter alia*, because of its departure from the statutory definition of bioequivalence. *See* Compl. ¶ 20. FDA finalized its redefinition of bioequivalence without alteration on April 20, 1992. *See* 57 Fed. Reg. 17,950 (1992).

FDA's abandonment of the statutory definition of bioequivalence would profoundly affect the agency's view of its ability to approve ANDAs for generic copies of pioneer drugs, and impact most directly on one class of drug products in which Schering is an active market participant. Schering is a research-based manufacturer of pharmaceutical products which sells, among many others, a variety of products whose effectiveness comes from topical application. These products, including the metered-dose inhaler Proventil®, a medication used in the treatment of asthma, are members of a class referred to as nonsystemically effective drugs, or "NSEDs." For a variety of reasons, establishing the bioequivalence of two NSEDs presents unique problems.[5] Under FDA's proposed regulations, however, these problems no longer exist because absorption—the touchstone of both FDA's

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[5] Absorption is more difficult to measure in the case of NSEDs because of their topical application. Blood concentrations—though necessary to measure in order to evaluate potential, unintended side effects—are smaller than those typically encountered with drugs, like pills, that enter the bloodstream through the digestive process. Proving equivalent topical absorption also presents difficult problems of measurement. The court of appeals stated, however, that there was no information in the record to the effect that proving bioequivalence for NSEDs generally was impossible. App., *infra*, 17a & n.12.

then-current regulations and the statute that codified them —no longer is a factor that must be considered. App., *infra*, 4a.

Schering believed that the decision to deviate from the statutory definition of bioequivalence was in violation of the Hatch-Waxman Amendments, and thus was unlawful. Schering also believed that the statutory bioequivalence standard could not be met for NSEDs given currently-available testing methodologies, and that FDA had relaxed the regulatory requirement in order that generics might nonetheless be approved.[6] The Company accordingly filed a citizen petition with FDA pursuant to 21 C.F.R. § 10.30 seeking, *inter alia*, to have the statutory definition of bioequivalence recognized by the agency and employed in all cases.

After the petition was denied in pertinent part, Schering filed suit in the U.S. District Court for the District of Columbia. The parties filed dispositive cross-motions and, in connection with a subsequently-filed motion for preliminary injunction prompted by an NSED approval, the district court entered judgment in favor of FDA. The court characterized the legal issue presented as "a significant one with legitimate arguments on both sides." App., *infra*, 35a. Applying the analysis of *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), the court concluded that the statute unambiguously required that bioequivalence *not* have an exclusive definition. First, the court observed a difference in wording between the statutory definition of bioequiv-

[6] Earlier in 1989, FDA had issued a "Guidance" to industry that stated the agency's intention to approve ANDAs for certain NSEDs (including Schering's Proventil®) based on a definition of bioequivalence that did not conform to that contained in the Hatch-Waxman Amendments. *See Guidance For In Vivo Bioequivalence Studies of Metaprotaranol Sulfate and Albuterol Inhalation Aerosols (Metered Dose Inhalers)*, Division of Bioequivalence, FDA (February 9, 1989).

alence and the adjacent definition of the related term, bioavailability, which even FDA agreed had an exclusive definition.[7] Bioavailability was defined using the definitional verb "means," which was not employed with respect to bioequivalence. The district court thought this difference was proof that Congress did not also intend that bioequivalence have an exclusive definition. In addition, the district court cited Section 355(j)(6)(A)(i)(III), which requires FDA to publish a list of all approved drugs and state for each whether *in vivo* (in the body) or *in vitro* (laboratory) tests will be adequate to establish bioequivalence. The court believed that the reference to *in vitro* testing "suggests" that bioequivalence did not depend upon evidence of absorption. App., *infra*, 40a-42a.

The district court also reviewed the legislative history. It concluded that Congress intended to "refine and extend" FDA's then-current generic drug approval procedures, and believed these procedures allowed FDA to employ definitions of bioequivalence that were not based upon absorption. The court did not review the FDA regulation, 21 C.F.R. § 320.1(e) (1977), that expressly defined bioequivalence. Rather, it surveyed various regulations regarding acceptable test methodologies that appeared to the court to permit bioequivalence (and bioavailability) to be shown without recourse to absorption. With this understanding, the court concluded in the alternative that FDA's interpretation of the statute was a reasonable one. App., *infra*, 43a-44a.

Schering appealed. Prior to oral argument, FDA's regulation redefining bioequivalence was promulgated in final form. The U.S. Court of Appeals for the District of Columbia Circuit subsequently ruled that this action mooted

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[7] "Bioavailability" refers to the rate and extent of absorption of a *single* drug product. *See* App., *infra*, 50a. Bioequivalence is simply the condition in which the bioavailabilities of *two* products are not materially different. *Id.* Thus, "bioequivalence is universally understood to mean comparable bioavailability." *Id.* at 16a n.10.

the litigation, and it invited Schering to pursue its legal claims in the context of a challenge to the final regulation. *See Schering Corp. v. Shalala,* 995 F.2d 1103 (D.C. Cir. 1993).

C. Proceedings in The District Court

On August 10, 1993, Schering filed suit against FDA in the United States District Court for the District of New Jersey. Schering's suit challenged FDA's regulations purporting to define bioequivalence, contending they were contrary to the plain language of the Hatch-Waxman Amendments, and were arbitrary, capricious, and an abuse of discretion.[8]

The district court issued its opinion on April 26, 1994, without having heard oral argument. The court first rejected FDA's claim (not advanced in the District of Columbia litigation) that Schering lacked standing. FDA argued that Schering's economic interest in seeing that the statutory safety and efficacy requirements were enforced was "antithetical" to the purposes of the Hatch-Waxman Amendments, which the agency saw as reflecting a dominant commitment to ensure that a generic copy of every pioneer drug was immediately approvable. *See* App., *infra*, 28a; FDA Br. 24, 25-27, 39-40, 42. The district court disagreed with FDA's views as to the statute's priorities and upheld Schering's standing to sue, holding that Congress had a "twin desire to insure the safety of the generic drugs approved via the abbreviated procedures." App., *infra*, 29a. On the merits, the district court adopted without elaboration the "reasoning" of the earlier decision of the U.S. District Court for the District of Columbia which had addressed a similar issue of statutory interpretation between the parties but which had subsequently been vacated as moot. *Id.* at 31a.

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[8] Schering sought declaratory and injunctive relief. In addition, it sought a ruling that certain proprietary and trade secret clinical testing data submitted in support of its pioneer NDAs were not yet subject to release pursuant to 21 U.S.C. § 355(*l*).

D. Proceedings in The Court of Appeals

Unlike the district court, which appeared to conclude that the statute is not ambiguous at all, the court of appeals quickly found ambiguity in the statutory language and turned, under the second part of *Chevron*, to a deferential review of the reasonableness of the agency's regulation. The court of appeals began, however, by concurring with the district court that Schering had standing to sue, again rejecting FDA's contention that Schering's economic interest in enforcing the statutory definition of bioequivalence conflicted with the allegedly paramount goal of ensuring that generic copies of every pioneer drug could be approved. The court concluded: "This action to enforce the terms of the Act comports with the congressional purpose that the statutory amendments passed to aid generic drug competition not diminish the safety of commercial drugs." *Id.* at 12a.

As to the merits, the court of appeals also employed the two-part test of *Chevron*. Looking first to the statutory text, the court disagreed that the minor difference in statutory language between the definitions of bioavailability and bioequivalence was significant. Distinguishing *Russello v. United States*, 464 U.S. 16 (1983), the court of appeals focused on the definitional language actually employed with respect to bioequivalence and found it "less precise" but fully consistent with a finding that Congress intended both bioavailability and bioequivalence to be exclusively defined terms. App., *infra*, 13a-15a.

The only other statutory provision cited by the court of appeals was Section 355(j)(6)(A)(i)(III), which requires a listing of whether *in vivo* or *in vitro* laboratory bioequivalence testing methodologies would be required for approval of an ANDA. The court believed that this provision "affirmatively suggests that means other than systemic absorption may be employed to ascertain . . . bioequivalence," and concluded that it "further confounds" the question whether Section 355(j)(7)(B) sets

forth an exclusive definition of bioequivalence. App., *infra*, 16a.

Having concluded that the statute was ambiguous, the court of appeals proceeded to the second part of the *Chevron* test, and asked whether FDA's assertion that Section 355(j)(7)(B) did not limit the agency's discretion to approve generic drugs was a "permissible construction of the Act." In conducting this inquiry, the court noted that the Hatch-Waxman Amendments "generally extend[ed]" the limited administrative procedure for generic drug approvals that existed prior to 1984. The court also cited FDA regulations that addressed potentially permissible "studies and tests," and inferred from these that FDA had previously asserted discretion to accord bioequivalence a flexible definition. For this reason, and because the court believed that the choice of testing methodologies for bioequivalence raised a technical issue, it concluded that it was required to defer to FDA as to whether Congress intended that the statutory bioequivalence requirement be an exclusive definition or merely a "safe harbor" enacted for the benefit of generic drug manufacturers. *Id.* at 5a, 17a-19a.

REASONS FOR GRANTING THE WRIT

Review by this Court is necessary because the court of appeals erred in allowing FDA to deprive the bioequivalence requirement of the one meaning given it by Congress, and because the court's decision is of demonstrable significance to a matter of legitimate national concern—the approval by FDA of safe and effective generic drugs. The decision of the court of appeals affects the entire generic drug approval process, and would allow FDA to free itself from a statutory obligation which Congress deemed, in that court's own words, "essential to the operation" of the statutory scheme. The bioequivalence requirement was added by the Hatch-Waxman Amendments, and defined, in order to be a congressionally-set threshold

of public health and safety that would have to be satisfied in the case of every generic drug approval. FDA, however, has deleted this specific threshold from the equation, substituting for the judicially-enforceable standard of bioequivalence enacted by Congress a grant of virtually unreviewable administrative discretion to employ such less stringent standard as it may deem appropriate. It has claimed the right to pick and choose among statutory commands, accepting a revolutionary increase in its authority to approve generic drugs while rejecting the limitations on that authority that the statute contains.

If the point were only that the decision as to how high the health and safety bar should be set was never for the agency to make in the first place, review by this Court would be warranted; the proper allocation of authority to decide how safe clinically untested generic drugs taken by millions of Americans must be is a matter of patent national concern. But more is at stake, and this Court's intervention is necessary to ensure that the principal change in the generic drug approval process made by Congress in 1984 is not undone by administrative fiat. What FDA has done with its 1992 regulatory redefinition of bioequivalence is take back precisely the discretion that Congress took from it in 1984. While the agency acknowledges its obligation to comply with the statutory "bioequivalence" requirement, it now accepts only the obligation to comply with a statutory requirement whose flexible, indefinite meaning is for it alone to determine. And the acknowledged effect of the new regulation, if not its acknowledged purpose, is to permit FDA to approve generic drugs that could not satisfy the definition of bioequivalence that Congress adopted, or for that matter the definition that even the agency itself had previously employed.

Viewed in terms of the *Chevron* analysis, it is apparent taking into account statutory language, structure, and legislative history, that the bioequivalence requirement of the

Hatch-Waxman Amendments is an exclusive definition, which FDA has no authority to ignore. The court of appeals' contrary interpretation is based upon an analysis that is incomplete and simply fails to construe the statute in the manner which this Court's precedents require. Unlike many statutes, the Hatch-Waxman Amendments dealt forthrightly with the policy decisions inherent in overhauling the generic drug approval process. Congress spoke to the question of how the bioequivalence requirement should be defined, and did not leave "ambiguous" the fundamental issue of whether the statute would or would not give substantive meaning to an essential element of the statutory scheme.

Beyond this, the court of appeals' conclusion that FDA's "safe harbor" theory of bioequivalence is a reasonable one is also wrong, for two reasons. First, as discussed above, it is based almost exclusively on the incorrect belief that the definition of bioequivalence codified by Congress was one which had whatever meaning FDA chose to give it. Second, it gives deference to an interpretation of the statute that focuses too narrowly on promotion of generic competition as the paramount objective and that as a consequence does not give adequate weight to the primacy of the legislation's clear health and safety concerns. The court of appeals indeed reached this very conclusion in rejecting FDA's claim that Schering lacked standing.

This Court's intervention is warranted to bring FDA's authority back within its banks on the important subject of generic drug approvals, and this case presents the appropriate occasion in which to perform the task. NSEDs, like the asthma drug, Proventil®, can be serious medicines used in life-threatening situations. If generic copies of any of them are being approved pursuant to unlawfully lax standards there should be no occasion for delay. Indeed, there is no reason to believe that a preferable vehicle for addressing this important question is

close at hand. Schering is aware of no other court challenge to FDA's regulatory redefinition of bioequivalence. And challenges on an approval-by-approval basis are made less likely because FDA does not typically disclose the definition of bioequivalence that it has applied in approving a generic drug. Schering, by contrast, has been disputing bioequivalence with FDA since 1989 and arrives at this Court with the legal issues cleanly and concretely presented, on appeal from a decision on dispositive cross-motions. If, as Schering believes, FDA is approving generic drugs in violation of its statutory authority, the time to remedy the situation is now.

I. THE THIRD CIRCUIT'S JUDGMENT THAT THE HATCH-WAXMAN AMENDMENTS DO NOT ESTABLISH A JUDICIALLY-ENFORCEABLE STANDARD FOR HEALTH AND SAFETY IN THE APPROVAL OF GENERIC DRUGS BY FDA IS CONTRARY TO THE STATUTE'S PLAIN LANGUAGE, STRUCTURE, AND LEGISLATIVE HISTORY

FDA's regulatory redefinition of bioequivalence is lawful only if consistent with congressional intent. "It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). Analysis of this question, in turn, is governed by the familiar standards of *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Where Congress has directly spoken to a question and has expressed its intent clearly, "that is the end of the matter;" the congressional intent must be implemented by agency and court alike. *Id.* at 842-43.

Construction of Section 355(j)(7)(B) begins with the ordinary meaning of the statutory language itself. *Landreth Timber Co. v. Landreth*, 471 U.S. 681 (1985).

Section 355(j)(7) consists in its entirety of the definitions of two interrelated terms, bioavailability and bioequivalence. The statute provides, in pertinent part:

> For purposes of this subsection:
>
> (A) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.
>
> (B) A drug shall be considered to be bioequivalent to a listed drug if—
>
> (i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses[.]

The most natural reading of Section 355(j)(7)(B), the bioequivalence provision, is as a definition, and FDA has expressly so characterized it. *See, e.g.*, 54 Fed. Reg. 28,872, 28,882 (1989). No statutory language counsels otherwise. The introductory phrase, "For purposes of this subsection," is of a type commonly used to introduce definitions, and indeed is so used in Chapter II ("Definitions") of the FDC Act itself. *See* 21 U.S.C. § 321 ("For the purposes of this chapter— . . . ."). The statute confers upon FDA no authority to establish alternative, looser definitions of terms so defined nor is there any textual basis, through use of a term such as "including," on which to conclude that the stated conditions of bioequivalence are not exclusive.

Similarly, the operative language with respect to bioequivalence itself—"[a] drug shall be considered to be bioequivalent to a listed drug if . . ."—is broad and mandatory, and is also a formulation used elsewhere in the FDC Act where substantive terms are given an exclusive definition. Indeed, an analogous structure appears in the

principal enforcement sections of the FDC Act—those authorizing FDA action to prevent the sale of adulterated or misbranded drugs or devices. *See* 21 U.S.C. § 351 ("A drug or device shall be deemed to be adulterated . . . [i]f . . . ."); *id.* § 352 ("A drug or device shall be deemed to be misbranded . . . [i]f . . . ."); *see also id.* § 453 (Poultry Products Inspection Act). FDA, without exception of which we are aware, has never obtained relief based on any theory that there are grounds for finding a drug adulterated or misbranded other than those expressly listed in the statute.

The court of appeals did not reject any of this analysis, and indeed reached conclusions that swept away the principal arguments advanced by the district court and FDA. Thus, the court of appeals rejected the district court's conclusion that the minor difference in wording between the statutory definitions of bioavailability and bioequivalence (the former, but not the latter, employs the definitional verb "means") had any significance. It affirmatively found, on the contrary, that the difference did not "preclude[] the conclusion that Congress intended section 355(j)(7)(B) to represent the exclusive standard to determine the bioequivalence of generic drugs to their pioneer drug counterparts." App., *infra*, 15a. The court of appeals can only be faulted on this score for not taking its analysis far enough, and failing to observe that the statutory definition of bioequivalence employs precisely the language and structure used elsewhere in the FDC Act to establish exclusive definitions of key statutory terms.

Similarly, while the court of appeals agreed with the parties that the statutory definition of bioequivalence codified the then-current FDA regulation defining bioequivalence, *id.* at 17a, it never examined that definition, and thus failed to recognize that it was dispositive of the issue at hand. The prior FDA regulation could not more clearly set forth an exclusive definition:

PART 320—BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

§ 320.1 Definitions

* * * *

(e) "Bioequivalent drug products" means pharmaceutical equivalents or pharmaceutical alternatives whose rate and extent of absorption do not show a significant difference when administered at the same molar dose of the therapeutic moiety under similar experimental conditions, either single dose or multiple dose. Some pharmaceutical equivalents or pharmaceutical alternatives may be equivalent in the extent of their absorption but not in their rate of absorption and yet may be considered bioequivalent because such differences in the rate of absorption are intentional and are reflected in the labeling, are not essential to the attainment of effective body drug concentrations on chronic use, or are considered medically insignificant for the particular drug product studied.

* * * *

21 C.F.R. § 320.1(e) (1977), App., *infra*, 52a. FDA indeed has held this regulation up as an example of how an exclusive definition could be crafted. *See* J.A. 31. Given FDA's agreement that Section 355(j)(7)(B) codifies this regulatory definition "in all pertinent respects," J.A. 19, no claim that the statutory definition was *non*-exclusive can survive.

So, too, the statutory structure also establishes the exclusivity of the definition of bioequivalence. The court of appeals itself recognized that "bioavailability" as set forth in Section 355(j)(7)(A) is a "clearly defined term," and that "bioequivalence is universally understood to mean comparable bioavailability." App., *infra*, 15a-16a & n.10. Schering argued that this linkage between interrelated terms required that bioequivalence also be deemed a

"clearly defined term," with the two adjacent statutory decisions interpreted *in pari materia*. If bioavailability can be understood only in terms of rate and extent of absorption, and bioequivalence *means* comparable bioavailability, in other words, then bioequivalence also can be found only with reference to rate and extent of absorption; if, as all agree, the one is an exclusive statutory definition, then so is the other. But the court of appeals never reached this issue. Rather, after confirming the exclusive definition of bioavailability and its linkage to bioequivalence, the court stumbled, characterizing as "peculiar" the fact that an exclusive definition would be conferred on the term (bioavailability) that was far less important in the statutory scheme. *Id.* at 15a. There is no peculiarity, of course, because Congress intended to confer an exclusive definition on *both* terms. The court of appeals nevertheless terminated its analysis at this point, apparently on the mistaken assumption that the legal question whether Congress intended a statutory definition to be binding on FDA raised a "difficult scientific issue." *Id.* 16a & n.10.

Indeed, the only aspect of statutory language and structure on which the court of appeals relied for its conclusion that the definition of bioequivalence is ambiguous is 21 U.S.C. § 355(j)(6)(A)(i)(III), which the court believed "affirmatively suggests that means other than systemic absorption may be employed to ascertain . . . bioequivalence." App., *infra*, 16a. As a threshold matter, Section 355(j)(6)(A)(i)(III) does not define bioequivalence and is not even a definitional provision. Nor does it govern FDA's decisionmaking in connection with generic drug approvals. Rather, it obligates FDA to publish for every approved drug a statement whether FDA will allow bioequivalence to be shown through *in vivo* (in the body) or *in vitro* (laboratory) tests. The provision provides no guidance as to the meaning of bioequivalence. The court of appeals believed, however, that "[*i*]*n*

vitro tests do not measure absorption," and inferred from the statutory authorization of *in vitro* bioequivalence tests that absorption must not be a necessary part of bioequivalence. *See* App., *infra,* 16a-17a & n.11.

The court's conclusion was wrong because its premise was faulty, as FDA itself has made clear. *In vitro* tests can be "correlated" with *in vivo* data, meaning in such case that an *in vitro* test is probative of everything that could be tested *in vivo.* Indeed, this point was made by FDA itself in responding to a citizen petition filed shortly after passage of the Hatch-Waxman Amendments. As FDA wrote, "[t]he in vitro dissolution studies submitted by the petitioner comparing the petitioner's product to the pioneer product are not correlated to any in vivo bioequivalence studies. They are thus not sufficient to demonstrate the bioequivalence of these products." *See Colmed Laboratories,* FDA Docket No. 85P-0421/CP at 4 (copy appended as addendum to Schering Reply Br.). Because *in vitro* tests may be probative of absorption, their inclusion as a permissible test methodology is not even remotely in conflict with a definition of bioequivalence that all other indicators point to as exclusive.

There is a wealth of textual evidence to the effect that Congress intended to give fixed, substantive content to the definition of bioequivalence. This evidence supports the only conclusion that could be drawn from the record as to Congress' intent. Prior to 1984, FDA was not obligated to require that bioequivalence be shown in connection with any generic drug approval. *See* 21 C.F.R. § 320.50- .52 (1977). Where it was required, bioequivalence had the fixed meaning that FDA regulations gave it. *See* 21 C.F.R. § 320.1(e) (1977). But because requiring bioequivalence was entirely discretionary, FDA as a practical matter possessed, and exercised, authority to approve ANDAs for products that were *not* bioequivalent

to the pioneer products they copied. The Hatch-Waxman Amendments did not codify this practice; they *ended* it.

For certain generic products, including many NSEDs, compliance with the bioequivalence requirement presented a challenge. Prior to the Hatch-Waxman Amendments this was no impediment to approval, since bioequivalence was discretionary.[9] After that legislation imposed a mandatory bioequivalence requirement, however, the question whether FDA would delay generic drug approvals until test methodologies could detect the products' absorption became an issue with which the agency had to deal. FDA's consideration of the issue was based on a view that Congress intended that a generic copy of every pioneer product be immediately approvable, and its decision was to water down the bioequivalence standard so that the impediment no longer existed. This decision still had to be squared with the statutory definition of bioequivalence, and so was born the theory that Section 355(j)(7)(B) established merely a safe harbor from which FDA was free to depart to employ less rigorous standards. The necessary byproduct of this theory was a construction of the Hatch-Waxman Amendments in which bioequivalence lost all substantive content.

The issues raised in this case are, accordingly, no mere debating points, and the importance of the court of appeals' decision extends beyond NSEDs potentially to all pioneer products. The difference between an exclusive definition of bioequivalence and a "definition" of bioequivalence that is merely a safe harbor is all the difference in the world. In the former case, FDA must conform its decisionmaking to a statutory health and safety standard in a manner capable of judicial review: Congress sets the standard and FDA determines whether

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[9] FDA's response to Schering's citizen petition identifies nine NSEDs for which generic drugs were approved prior to 1984 pursuant to criteria that were published in the Federal Register. J.A. 18. *None* required a showing of bioequivalence.

it has been met with respect to a particular generic drug application. In the latter case, the agency determines not only how a standard may be met but what the standard means to begin with: a model of virtually unreviewable discretion. To the extent the court of appeals allows FDA to read out of the Hatch-Waxman Amendments a judicially-enforceable definition of bioequivalence, the agency may again approve generic drugs pursuant to any standard which it deems appropriate. In the process, FDA recaptures the authority Congress took from it: the authority to approve generic drugs that are not *bioequivalent* to their pioneers. Congress could not have changed the law to impose a mandatory, unwaivable bioequivalence requirement, and addressed its meaning, only to intend that the courts allow FDA to determine that the agency is free to do as it wishes after all.

II. FDA'S CONSTRUCTION OF THE HATCH-WAXMAN AMENDMENTS IS NOT A PERMISSIBLE ONE

Having concluded (erroneously, in Schering's view) that the statutory definition of bioequivalence was ambiguous, the court of appeals correctly understood that its job was not over, and that it was required to overrule any construction of the statute that was not "permissible." App., *infra*, 17a (quoting *Chevron*, 467 U.S. at 842-43). Deference to an administrative construction of an ambiguous term is appropriate only where that interpretation "is reasonable in light of the legislature's revealed design." *NationsBank of North Carolina, N.A. v. Variable Annuity Life Ins. Co.*, 115 S. Ct. 810, 813-14 (1995). The court of appeals did not, however, discharge its obligation of judicial review in this case. It made clear errors in reviewing the regulatory history of bioequivalence, and failed to examine or respect the purposes of the bioequivalence requirement.

A. The Court of Appeals Mistakenly Concluded That FDA's Construction Of The Bioequivalence Requirement Was Consistent With Congress' Codification Of FDA's Pre-Hatch-Waxman Authority

The court of appeals considered FDA's construction of the bioequivalence requirement to be reasonable because it believed that construction to be consistent with Congress' intent to extend "generally" the agency's pre-Hatch-Waxman practices. App., *infra*, 18a. In arriving at this conclusion, the court looked to FDA's 1977 regulations (which were in force in 1984) and believed that it found in those regulations evidence that the agency had considered the definition of bioequivalence to be non-exclusive. Assuming for the moment, as did the court of appeals, that Congress intended to codify FDA's prior practices *in toto*, the court's conclusion would be wrong for the reasons stated in the previous section: FDA historically had not viewed bioequivalence as it now claims, but instead when it chose to require bioequivalence gave that term a fixed, definite meaning, as its own 1977 regulatory definition of the term makes plain. *See* App., *infra*, 52a.

Oddly, in searching for FDA's understanding of the bioequivalence requirement in 1984, the court of appeals did not review the best available evidence: the regulatory definition itself. Rather, the court focused on the fact that in certain *non-definitional* sections of the same regulation FDA listed "several studies and tests required for approval" which, presumably, the court believed reflected an ability to employ different definitions of bioequivalence. *Id.* at 19a. But surely this is irrelevant. Schering does not dispute that, once FDA had decided to require a showing of bioequivalence with respect to a particular ANDA, it had discretion to determine the technical question of what "studies and tests" it wanted applicants to conduct. What Schering does dispute is that, having given bioequivalence an exclusive definition in an adjoining

regulation, FDA was free to make applicants satisfy a different one.

B. The Court of Appeals Was Wrong To Defer To A Construction Of The Bioequivalence Requirement That Conflicted With Congress' Intent

Deference should not be paid to FDA's construction of the bioequivalence requirement for the additional reason that FDA has fundamentally misunderstood Congress' purpose in imposing the requirement in the first place, overemphasizing pro-generic commercial interests and underemphasizing the paramount health and safety goals of the statute. FDA advised the court of appeals that, in its view, "[t]he bioequivalence provisions of the Hatch-Waxman Amendments were intended to ease the entry of generic drugs into the market, not constrain competition." FDA Br. at 42. This conception of the bioequivalence requirement was consistent with FDA's belief that any construction of the statute that interfered with the supposed imperative to approve a generic copy of every pioneer product would have to give way. *See, e.g., id.* at 26 (rejecting any construction of bioequivalence that was not capable of being satisfied for every pioneer drug in 1984).

The court of appeals, however, would have none of it. The court rejected FDA's belief that the bioequivalence requirement existed to "ease" generic drug approvals and recognized, to the contrary, that maintenance of the statutory health and safety standard took precedence over the commercial goals of the statute.[10] FDA indeed held a skewed view of the purpose of the bioequivalence requirement. The question presented under the second part of the *Chevron* test, accordingly, is whether it is appropriate for a court to defer to an agency that has such

[10] As the court of appeals stated, "the fact that actions by [pioneer drug manufacturers] may thwart the competing congressional purpose of easing the entry of generic drugs into the market is subsumed by the overriding necessity of ensuring public access to safe commercial drugs." App., *infra*, 12a-13a.

a demonstrably incorrect view of the law. Clearly the answer to that question is no.

It is long-settled that courts are obligated to review regulations to ensure that the agency has considered the right factors in reaching its decision, and to vacate regulations as arbitrary and capricious where "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, . . . or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983); *cf. Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). The principal source of guidance to the agency must, of course, be its enabling statute. *Pension Benefit Guaranty Corp. v. LTV Corp.*, 496 U.S. 633, 645-47 (1990); *Brewer v. Madigan*, 945 F.2d 449, 457 (1st Cir. 1991). Regulations that would alter the policy choices made by Congress must be struck down. *American Textile Mfrs. Inst. v. Donovan*, 452 U.S. 490, 509 (1981) ("Any [regulatory] standard based on a balancing of costs and benefits by the Secretary that strikes a different balance than that struck by Congress would be inconsistent with the [statutory] command . . . ."); *see* Laurence H. Silberman, *Chevron-The Intersection Of Law And Policy*, 58 Geo. Wash. L. Rev. 821, 827-28 (1990) ("In either the second step of *Chevron* or in arbitrary and capricious review, the court often asks itself whether the agency considered and weighed the factors Congress wished the agency to bring to bear on its decision.").

It is indeed for agencies and not for courts to balance competing statutory interests so as best to serve congressional intent. But the judicial role exists to ensure that agencies take the correct factors into account, and do not weigh them in a manner demonstrably contrary to Congress' aims. "If the [agency's] choice represents a reasonable accommodation of conflicting policies that

were committed to the agency's care by the statute, we should not disturb it unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned." *Chevron*, 467 U.S. at 845 (quoting *United States v. Shimer*, 367 U.S. 374, 383 (1961)). Here, FDA's construction is based upon a lopsided view of the bioequivalence requirement that the court of appeals itself concluded Congress had not intended. *Chevron* cannot mean that a court faced with so demonstrably an incorrect vision of Congress' intent is powerless to intervene.

CONCLUSION

For the foregoing reasons, the Petition For Certiorari should be granted.

Respectfully submitted,

ROBERT P. REZNICK
Counsel of Record
HUGHES HUBBARD & REED
1300 I Street, N.W.
Suite 900 West
Washington, D.C. 20005
(202) 408-3740
Counsel for Petitioner

Of Counsel

JOSEPH C. CONNORS
MAUREEN O. CHELIUS
SCHERING CORPORATION
2000 Galloping Hill Road
Kenilworth, NJ 07033
(908) 298-4741